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10/642,348	08/15/2003	Keith K. Daellenbach	BJT 332B	1593

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EXAMINER

SCHELL, LAURA C

ART UNIT	PAPER NUMBER
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3767

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	04/20/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary	Application No. 10/642,348	Applicant(s) DAELLENBACH, KEITH K.	
	Examiner Laura C. Schell	Art Unit 3767	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 23 January 2007.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-11, 13-20, 23 and 27-31 is/are pending in the application.
- 4a) Of the above claim(s) 18-20, 27, 28, 30 and 31 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-11, 13-17, 23 and 29 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 15 August 2003 is/are: a) ☐ accepted or b) ☒ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--------------------------------------------------------------------------------------|-------------------------------------------------------------------|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 9 recites the limitation "orifices" in line 1. There is insufficient antecedent basis for this limitation in the claim. Claim 9 depends from claim 1, which recites "orifice".

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

The changes made to 35 U.S.C. 102(e) by the American Inventors Protection Act of 1999 (AIPA) and the Intellectual Property and High Technology Technical Amendments Act of 2002 do not apply when the reference is a U.S. patent resulting directly or indirectly from an international application filed before November 29, 2000. Therefore, the prior art date of the reference is determined under 35 U.S.C. 102(e) prior to the amendment by the AIPA (pre-AIPA 35 U.S.C. 102(e)).

Claims 1, 6, 7 and 23 are rejected under 35 U.S.C. 102(e) as being anticipated by Hauschild et al. (US Patent No. 6,905,475). Hauschild discloses a needle-free jet injection device (see abstract, lines 5-11) for delivering a fluid into an internal organ, the device comprising: a rigid end effector (Fig. 6, 27; also see col. 4, lines 34-35) having a blunt distal end (Fig. 6 discloses that the end of the effector is blunt, and furthermore, the Oxford online dictionary's definition of "blunt" is: "having a flat or rounded end" which, as Fig. 6 demonstrates, the end(s) of the end-effector is/are rounded. {http://www.askoxford.com/concise_oed/blunt?view=uk}) and including at least one injection orifice (90) disposed on a sidewall of the end effector, the end effector having a longitudinal axis configured into a shape wherein the end effector is sufficiently rigid to maintain the shape of its longitudinal axis during use (col. 4, lines 34-35); the end effector being adapted to be positioned within a prostatic section of a patient's urethra adjacent the patient's prostate gland wherein the at least one injection orifice is oriented generally laterally to the longitudinal axis of the end effector (Fig. 6; col. 5, line 56 through col. 6, line 13); a fluid reservoir (Figs. 9 and 10, 86) in fluid communication with the end effector; and an ejection mechanism (Figs. 9 and 10) adapted to eject the fluid from the fluid reservoir through the end effector and out of the injection orifice with sufficient pressure to penetrate the prostate gland while preserving functionality of the prostate gland (col. 5, line 56 through col. 6, line 13; col. 6, line 35 through col. 7, line 27).

In reference to claim 6, Hauschild discloses that the ejection mechanism is further adapted to allow the device to eject multiple doses of fluid without refilling the

fluid reservoir (Figs. 3 and 4 disclose that a syringe can be used and therefore is capable of providing multiple doses without refilling; also see col. 3, lines 37-41 which disclose that multiple injections can be made to the various lobes of the prostate within the same procedure).

In reference to claim 7, Hauschild discloses that the fluid includes ethanol (see abstract).

In reference to claim 23, Hauschild discloses that the shape of the longitudinal axis of the end effector is generally straight (Figs. 3, 4 and 6).

Claim 18 is rejected under 35 U.S.C. 102(e) as being anticipated by Hauschild et al. (US Patent No. 6,905,475). Hauschild discloses a needle-free jet injection device for delivering a fluid into selected internal tissue (see abstract, lines 5-11), the device comprising: a rigid end effector (Fig. 6, 27; also see col. 4, lines 34-35) having a blunt distal end (Fig. 6 discloses that the end of the effector is blunt, and furthermore, the Oxford online dictionary's definition of "blunt" is: "having a flat or rounded end" which, as Fig. 6 demonstrates, the end(s) of the end-effector is/are rounded.

{http://www.askoxford.com/concise_oed/blunt?view=uk}) and at least one injection orifice (90) disposed on a sidewall of the end effector, the end effector being adapted to be positioned with the injection orifice adjacent the selected internal tissue, the end effector having a longitudinal axis configured to a shape wherein the end effector is sufficiently rigid to maintain the shape of its longitudinal axis during use (col. 4, lines 34-35), wherein the at least one injection orifice is oriented generally laterally to the longitudinal axis of the end effector (Fig. 6, 90); and a fluid reservoir (Figs. 9 and 10, 86)

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in fluid communication with the end effector; and an ejection mechanism adapted to eject the fluid from the fluid reservoir through the end effector and out of the injection orifice with sufficient pressure to penetrate the selected internal tissue while preserving functionality of the tissue, wherein the ejection mechanism may be adjusted to provide an appropriate system pressure for the selected internal tissue (col. 5, line 56 through col. 6, line 13; col. 6, line 35 through col. 7, line 27).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 2-5 and 8-10 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hauschild et al. (US Patent No. 6,905,475) in view of Paskar (US Patent No. 6,623,449).

In reference to claims 2-5, Hauschild discloses the device substantially as claimed, including a rigid end effector (Fig. 6) and an injection orifice (90) located in the distal section of the straight shaft (Fig. 6), however, Hauschild does not disclose that the end effector includes a plurality of injection orifices. Paskar, however, discloses a jet injection system (Fig. 16) which has a plurality of injection orifices (134) located at the distal section. Therefore it would have been obvious to one of ordinary skill in the art at the time of the invention to have modified Hauschild with the plurality of injection orifices, as taught by Paskar, in order to be able to treat the entire prostate and once for a faster procedure.

In reference to claims 8-10, Hauschild discloses the device substantially as claimed including an injection orifice, however Hauschild does not disclose that the injection orifices are arranged linearly or in multiple offset rows. Paskar, however, discloses a jet injector system (Fig. 16) which includes injection orifices (134) arranged linearly and in multiple offset rows along the length of the end effector. Therefore it would have been obvious to one of ordinary skill in the art at the time of the invention to have modified Hauschild with the plurality of injection orifices and the arrangement of the orifices, as taught by Paskar, in order to provide an end effector that can treat a greater surface area of tissue without missing portions of the tissue to be treated, thus creating a shorter treatment time.

Claims 11 and 13-17 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hauschild et al. (US Patent No. 6,905,475) in view of Paskar (6,623,449).

Hauschild discloses the device substantially as claimed including: a needle-free jet

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injection device for delivering a fluid into an internal organ (see abstract, lines 5-11), the device comprising: a fluid reservoir (Figs. 9 and 10, 86); a longitudinally rigid extension structure (Fig. 6, 27; also see col. 4, lines 34-35) adapted to be inserted within a patient's urethra so that a distal region of the extension structure is positioned adjacent the patient's prostate gland (Fig. 6; col. 5, line 56 through col. 6, line 13), wherein the distal region of the extension has an at least partially hollow interior that fluid communicates with the fluid reservoir (Fig. 6), wherein the extension structure is sufficiently rigid to maintain a longitudinal shape during use (col. 4, lines 34-35), wherein the distal region has a blunt distal end (Fig. 6 discloses that the end of the effector is blunt, and furthermore, the Oxford online dictionary's definition of "blunt" is: "having a flat or rounded end" which, as Fig. 6 demonstrates, the end(s) of the end-effector is/are rounded. {http://www.askoxford.com/concise_oed/blunt?view=uk}); and an ejection mechanism (Figs. 9 and 10) adapted to eject the fluid from the fluid reservoir (86) through the extension structure and out of an injection orifice (Fig. 6, 90) provided in a sidewall of the distal region of the extension structure with sufficient pressure to penetrate the prostate gland while preserving functionality of the prostate gland, wherein the orifice is oriented in a direction generally lateral to a longitudinal axis of the extension structure (Fig. 6, 90). Hauschild, however, does not disclose that the extension structure includes a plurality of orifices. Paskar, however, discloses a jet injection system (Fig. 16) with an end effector (Fig. 131) that has a plurality of jet injection orifices arranged in the side wall of the end effector (134). Therefore it would have been obvious to one of ordinary skill in the art at the time of the invention to have

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modified Hauschild with the plurality of orifices, as taught by Paskar, in order to provide an end effector that is capable of treating a larger surface area of the prostate in one treatment, in order to provide a faster treatment.

In reference to claims 13-17, Hauschild discloses the device substantially as claimed, including that the fluid contains ethanol (see abstract). Hauschild, however, does not disclose a plurality of injection orifices arranged in offset rows. Paskar, however, discloses that the injection orifices (134) are arranged linearly in multiple offset rows (Fig. 16) along the length of the end effector, and that they are oriented in a direction generally lateral to a longitudinal axis of the distal region of the extension structure (Fig. 16). Therefore it would have been obvious to one of ordinary skill in the art at the time of the invention to have modified Hauschild with the arrangement of the plurality of orifices, as taught by Paskar, in order to provide an end effector that is capable of treating a larger surface area, without missing portions of the prostate, which would be avoided with the offset rows, in order to provide a more efficient treatment.

Claims 19, 20 and 26-28 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hauschild et al. (US Patent No. 6,905,475) in view of Kollias et al. (US Patent No. 6,251,099). Hauschild discloses the device substantially as claimed including an injection mechanism in which the injection pressure can be adjusted and selected (Figs. 9 and 10; col. 6, line 35 through col. 7, line 27), however, Hauschild does not disclose a mechanism configured to provide a rise time to a peak pressure wherein the rise time and peak pressure selection are to preserve tissue functionality. Kollias, however, discloses a needle-less injection device in which the peak injection

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pressures and rise time to these pressures can be selected in order to preserve the functionality of the tissue (col. 1, lines 55-64). Therefore it would have been obvious to one of ordinary skill in the art at the time of the invention to have modified Hauschild with the rise time and peak pressure selection of Kollias, in order to provide a safe and customizable medical device.

Response to Arguments

Applicant's arguments with respect to claims 1-11, 13-20 and 26-28 have been considered but are moot in view of the new ground(s) of rejection.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Laura C. Schell whose telephone number is (571) 272-7881. The examiner can normally be reached on Monday-Friday 8am-4:30pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Kevin Sirmons can be reached on (571) 272-4965. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

LCS

DETAILED ACTION

Election/Restrictions

Claims 18-20, 27, 28, 30 and 31 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected species, there being no allowable generic or linking claim. In applicant's election of species response of 8/13/2004, applicant elected to pursue species C. The amendment to claim 18 and consequently dependent claims 19, 20, 27, 28, 30 and 31 are drawn to species G. Therefore these claims are being withdrawn as they are no longer directed towards species C.

Drawings

The drawings are objected to under 37 CFR 1.83(a). The drawings must show every feature of the invention specified in the claims. Therefore, the "plunger powered by a gas cartridge" in claim 11 must be shown or the feature(s) canceled from the claim(s). No new matter should be entered.

Corrected drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. The figure or figure number of an amended drawing should not be labeled as "amended." If a drawing figure is to be canceled, the appropriate figure must be removed from the replacement sheet,

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and where necessary, the remaining figures must be renumbered and appropriate changes made to the brief description of the several views of the drawings for consistency. Additional replacement sheets may be necessary to show the renumbering of the remaining figures. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either "Replacement Sheet" or "New Sheet" pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

Specification

The specification is objected to as failing to provide proper antecedent basis for the claimed subject matter. See 37 CFR 1.75(d)(1) and MPEP § 608.01(o). Correction of the following is required: "between about 643 psig and about 2001 psig".

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claim 1 and consequently dependent claims 2-10 and 23 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the

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inventor(s), at the time the application was filed, had possession of the claimed invention. The specification does not provide support for the range "between 643 psig and 2001 psig". Rather, the specification only discloses that experiments were carried out at specific pressures, such as at 1030 and 2001 psig in lines 20-21 of page 16, and at 643 psig in line 9 of page 17. The specification also discloses that the injection system was specifically adjusted to carry out the injections at these specific pressure levels. The only other portion of the specification that discloses pressure levels is in lines 10-11 of page 16 (the system was modified to have a average peak pressure of 1030) and at lines 6-7 of page 18 (the system was modified to have an average peak pressure of 1011). Therefore the specification discloses that the system was used at individual pressures, and not in a range of between 643-2001 psig. Furthermore, there is not support for the words "*about* 643 psig" and "*about* 2001 psig". The words "about" have not been found in the specification in conjunction with the pressures claimed.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1 and consequently dependent claims 2-10 and 23 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. It is unclear what applicant means by "between *about* 643 psig and *about* 2001 psig". As the specification does not disclose a range of pressures higher and lower than 2001 and

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643 psig, respectively, it is unclear what kind of pressure range "about" encompasses.

For example, is 640 psig about 643 psig? And is 2500 or 3000 psig about 2001 psig?

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 1-10 and 23 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hauschild et al. (US Patent No. 6,905,475) in view of Glines et al. (US Patent No. 6,716,190). Hauschild discloses a needle-free jet injection device (see abstract, lines 5-11) for delivering a fluid into an internal organ, the device comprising: a rigid end effector (Fig. 6, 27; also see col. 4, lines 34-35) having a blunt distal end (Fig. 6 discloses that the end of the effector is blunt, and furthermore, the Oxford online dictionary's definition of "blunt" is: "having a flat or rounded end" which, as Fig. 6 demonstrates, the end(s) of the end-effector is/are rounded.

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{http://www.askoxford.com/concise_oed/blunt?view=uk}) and including at least one injection orifice (90) disposed on a sidewall of the end effector, the end effector having a longitudinal axis configured into a shape wherein the end effector is sufficiently rigid to maintain the shape of its longitudinal axis during use (col. 4, lines 34-35); the end effector being adapted to be positioned within a prostatic section of a patient's urethra adjacent the patient's prostate gland wherein the at least one injection orifice is oriented generally laterally to the longitudinal axis of the end effector (Fig. 6; col. 5, line 56 through col. 6, line 13); a fluid reservoir (Figs. 9 and 10, 86) in fluid communication with the end effector; and an ejection mechanism (Figs. 9 and 10) adapted to eject the fluid from the fluid reservoir through the end effector and out of the injection orifice with sufficient pressure to penetrate the prostate gland while preserving functionality of the prostate gland (col. 5, line 56 through col. 6, line 13; col. 6, line 35 through col. 7, line 27).

Hauschild, however, while disclosing that the ejection mechanism is adapted to eject the fluid through the end effector and injection orifice at a high pressure (col. 5, line 56 through col. 6, line 34 disclose that the embodiments of Figs. 6-8 are distinct in that they deliver ethanol at a high pressure), Hauschild does not disclose that the pressure is between 643 psig and 2001 psig. Glines, however, discloses a needle-free jet injection device for delivering fluid into an internal organ (abstract and col. 4, lines 26-34). Glines further discloses that the needle-free injection device is capable of delivering/ejecting the fluid at a pressure of between 1800 and 2300 psi wherein part of the range (1800-2001) falls within the range claimed. Therefore it would have been

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obvious to one of ordinary skill in the art at the time of the invention to have modified Hauschild with the high pressure ejection mechanism and specific pressure ranges, as taught by Glines, in order to provide a device that is capable of delivering the fluid at a high enough pressure that it would penetrate the tissue and be therapeutic (abstract), especially since Hauschild discloses that the fluid is delivered by a high-powered source.

In reference to claims 2-5 and 8-10, Hauschild discloses the device substantially as claimed including a rigid end effector (Fig. 6) and an injection orifice (90) located in the distal section of the straight shaft (Fig. 6), however, Hauschild does not disclose that the end effector includes a plurality of injection orifices. Glines, however, discloses a rigid end effector with a straight shaft and distal section and a plurality of orifices in the distal section (Figs. 12 and 14a and 14b). Glines further discloses that the injection orifices are arranged linearly along the length of the end effector (Figs. 12, 14 and 14b), also arranged in multiple rows (Figs. 14a and 14b) and that the rows are offset from each other (Figs. 14a and 14b). Therefore it would have been obvious to one of ordinary skill in the art at the time of the invention to have modified Hauschild with the plurality of orifices and their arrangement, as taught by Glines, in order to provide an end effector that is capable of treating a larger surface area of the prostate in one treatment.

In reference to claim 6, Hauschild discloses that the ejection mechanism is further adapted to allow the device to eject multiple doses of fluid without refilling the fluid reservoir (Figs. 3 and 4 disclose that a syringe can be used and therefore is

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capable of providing multiple doses without refilling; also see col. 3, lines 37-41 which disclose that multiple injections can be made to the various lobes of the prostate within the same procedure).

In reference to claim 7, Hauschild discloses that the fluid includes ethanol (see abstract).

In reference to claim 23, Hauschild discloses that the shape of the longitudinal axis of the end effector is generally straight (Figs. 3, 4 and 6).

Claims 11 and 13-17 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hauschild et al. (US Patent No. 6,905,475) in view of Glines et al. (US Patent No. 6,716,190). Hauschild discloses the device substantially as claimed including: a needle-free jet injection device for delivering a fluid into an internal organ (see abstract, lines 5-11), the device comprising: a fluid reservoir (Figs. 9 and 10, 86); a longitudinally rigid extension structure (Fig. 6, 27; also see col. 4, lines 34-35) adapted to be inserted within a patient's urethra so that a distal region of the extension structure is positioned adjacent the patient's prostate gland (Fig. 6; col. 5, line 56 through col. 6, line 13), wherein the distal region of the extension has an at least partially hollow interior that fluid communicates with the fluid reservoir (Fig. 6), wherein the extension structure is sufficiently rigid to maintain a longitudinal shape during use (col. 4, lines 34-35), wherein the distal region has a blunt distal end (Fig. 6 discloses that the end of the effector is blunt, and furthermore, the Oxford online dictionary's definition of "blunt" is: "having a flat or rounded end" which, as Fig. 6 demonstrates, the end(s) of the end-effector is/are

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rounded. {http://www.askoxford.com/concise_oed/blunt?view=uk}); and an ejection mechanism (Figs. 9 and 10) adapted to eject the fluid from the fluid reservoir (86) through the extension structure and out of an injection orifice (Fig. 6, 90) provided in a sidewall of the distal region of the extension structure with sufficient pressure to penetrate the prostate gland while preserving functionality of the prostate gland, wherein the orifice is oriented in a direction generally lateral to a longitudinal axis of the extension structure (Fig. 6, 90).

Hauschild, however, does not disclose that the extension structure includes a plurality of orifices or the ejection mechanism being a plunger powered by a gas cartridge. Glines, however, discloses a jet injection system with an end effector that has a plurality of jet injection orifices arranged in the side wall of the end effector (Fig. 12) as well as a jet injection system with an end effector that has a plurality of jet injection orifices arranged at the distal end (Fig. 8c). Glines further discloses that the needle-free jet injection device has an ejection mechanism that powered by a gas cartridge (col. 4, line 59 through col. 5, line 9). Therefore it would have been obvious to one of ordinary skill in the art at the time of the invention to have modified Hauschild with the plurality of orifices and the ejection mechanism powered by a gas cartridge, as taught by Glines, in order to provide an end effector that is capable of treating a larger surface area of the prostate in one treatment, in order to provide a faster treatment as well as to provide a high-pressure power source to deliver the fluid into the tissue at a high pressure with out the need of a needle (abstract).

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In reference to claims 13-17 and 29, Hauschild discloses the device substantially as claimed, including that the fluid contains ethanol (see abstract). Hauschild, however, does not disclose a plurality of injection orifices arranged in offset rows or that the gas cartridge is a replaceable carbon dioxide cartridge. Glines, however, discloses that the injection orifices (Fig. 14a and 14b, 422) are arranged linearly in multiple offset rows along the length of the end effector, and that they are oriented in a direction generally lateral to a longitudinal axis of the distal region of the extension structure (Figs. 14a and 14b). Glines further discloses that the gas cartridge is a replaceable carbon dioxide cartridge (col. 4, lines 64-65). Therefore it would have been obvious to one of ordinary skill in the art at the time of the invention to have modified Hauschild with the arrangement of the plurality of orifices, as taught by Glines, in order to provide an end effector that is capable of treating a larger surface area, without missing portions of the prostate, which would be avoided with the offset rows, in order to provide a more efficient treatment and provide a medically safe gas to power the injections.

Response to Arguments

Applicant's arguments with respect to claims 1-11, 13-20 and 27-31 have been considered but are moot in view of the new ground(s) of rejection.

With regards to the 37 CFR 1.132 affidavit, the affidavit has been reviewed but is moot in view of the fact that the pressures relied upon in amended claim 1 are considered to be new matter (see rejection above).

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Laura C. Schell whose telephone number is (571) 272-7881. The examiner can normally be reached on Monday-Friday 9am-5:30pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Kevin Sirmons can be reached on (571) 272-4965. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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KEVIN C. SIRMONS
SUPERVISORY PATENT EXAMINER

A handwritten signature in cursive script, reading "Kevin C. Sirmons", positioned below the printed name and title.